

TAB 5

LEXSEE 1995 U.S. DIST. LEXIS 4916

**LIFESCAN, INC., a California corporation, Plaintiff, v. POLYMER
TECHNOLOGY INTERNATIONAL CORPORATION, a Washington corporation,
Defendant.**

NO. C94-672R

**UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF
WASHINGTON**

1995 U.S. Dist. LEXIS 4916; 35 U.S.P.Q.2D (BNA) 1225

**January 3, 1995, Decided
January 3, 1995, FILED, ENTERED**

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JUDGES: [*1] BARBARA J. ROTHSTEIN, UNITED STATES DISTRICT JUDGE

OPINIONBY: BARBARA J. ROTHSTEIN

OPINION:

ORDER ON PENDING MOTIONS: SUMMARY JUDGMENT MOTIONS, MOTION TO AMEND ANSWERS, AND PRELIMINARY INJUNCTION MOTION

THIS MATTER comes before the court on the various motions listed below. Having considered the pleadings filed in support and in opposition to the motions, and having held oral argument, the court finds and rules as follows:

I. BACKGROUND

Plaintiff LifeScan, Inc. ("LifeScan") is a corporation which has developed a home use blood glucose monitoring system which is sold commercially, primarily to persons with diabetes who use it to monitor the level of glucose (sugar) in their blood. The meters sold by LifeScan are called One Touch meters, while the strips sold for use in the meters are called One Touch test strips. LifeScan has sought and received patents for various components of its monitoring system. The patents at issue in the pending motions are as follows: No. 5,304,468, ("the '468 patent"); No. 4,935,346, known as ("the '346 patent"); and No. 5,049,487, ("the '487 patent"). This case concerns claims by LifeScan and defendant Polymer Technology International Corp. ("Polymer") concerning [*2] the three above-named patents. Polymer is a corporation which manufactures and sells blood glucose test strips, called First Choice strips, to be used in the One Touch blood glucose meters made and sold by LifeScan.

LifeScan claims that Polymer is infringing its home-use blood glucose monitoring patents. Polymer has presented various defenses to LifeScan's claims of patent infringement, including allegations that the patents themselves are invalid; that users of the LifeScan meters have an implied license to use Polymer's testing strips; and

that LifeScan has misused its patents and therefore Polymer is not liable for infringement. In connection with their various claims and defenses, the parties have filed the following motions which will be addressed below: LifeScan's Motion for Summary Judgment of Literal Infringement of the '468 Patent; LifeScan's Motion for Summary Judgment of No Implied License for the '468 Patent; Polymer's Motion for Summary Judgment of Invalidity of the '468 Patent Pursuant to 35 U.S.C. Sec. 112; Polymer's Motion for Summary Judgment of Invalidity of the '468 Patent Under 35 U.S.C. Secs. 102(b) and 103; LifeScan's Motion for Summary Judgment of Literal Infringement [*3] of the '346 and '487 Patents; Polymer's Motion for Summary Judgment of Non-Infringement of the '346 and '487 Patents; and LifeScan's Motion for Summary Judgment of No Misuse of the Three Patents at Issue. In addition, Polymer has moved to amend its answers to the complaints which give rise to this matter. Finally, LifeScan has moved for a preliminary injunction with respect to the '468 patent.

II. DISCUSSION

A. Summary Judgment Standard

Summary judgment is proper is "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Fed.R.Civ.P.* 56(c); *Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 248-50, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986). The moving party bears the initial burden of demonstrating that it is entitled to summary judgment, *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986), after which the burden shifts to the non-moving party to show that there is a genuine issue of material fact. *Id.* at 322-23. "To create a genuine issue [*4] of fact, the nonmovant must do more than present some evidence it asserts is disputed." *Avia Group Int'l, Inc. v. L.A. Gear California*, 853 F.2d 1557, 1560 (Fed. Cir. 1988) (emphasis in original). There must be sufficient evidence presented "favoring the nonmoving party for a jury to return a verdict for that party. If the evidence [of the non-movant] is merely colorable, or is not significantly probative, summary judgment may be granted." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249-50, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986) (citations omitted); see also *Celotex*, 477 U.S. at 322-23.

B. The '468 Patent

The following motions relate to LifeScan's '468 patent, which was issued April 19, 1994: LifeScan's Motion for Summary Judgment of Literal Infringement of the '468 Patent; LifeScan's Motion for Summary Judgment of No Implied License for the '468 Patent; Polymer's

Motion for Summary Judgment of Invalidity of the '468 Patent Pursuant to 35 U.S.C. Sec. 112; and Polymer's Motion for Summary Judgment of Invalidity of the '468 Patent Under 35 U.S.C. Secs. 102(b) and 103. The court will address each of these motions in turn.

1. LifeScan's Motion for [*5] Summary Judgment of Literal Infringement of the '468 Patent

By statute, "whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent." 35 U.S.C. Sec. 271(a). Through the patent laws, "Congress [has] recognized that it is necessary to grant temporary monopolies on inventions in order to induce those skilled in the 'useful arts' to expend the time and money necessary to research and develop new products . . ." *Eli Lilly & Co. v. Premo Pharmaceutical Labs., Inc.*, 630 F.2d 120, 137 (3d Cir.), cert. denied, 449 U.S. 1014, 66 L. Ed. 2d 473, 101 S. Ct. 573 (1980). LifeScan has the burden of proving infringement by a preponderance of the evidence. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1054 (Fed. Cir.), cert. denied, 488 U.S. 825, 102 L. Ed. 2d 51, 109 S. Ct. 75 (1988).

The parties agree that in order to determine whether or not a patent has been literally infringed, the court follows a two-step process. *Autogiro Co. of Amer. v. U.S.*, 181 Ct. Cl. 55, 384 F.2d 391, 401 (Ct. Cl. 1967). First, the court must ascertain the proper meaning or interpretation of [*6] the patent claims themselves. *Id.*; see also *Corning Glass Works v. Sumitomo Electric U.S.A., Inc.*, 868 F.2d 1251, 1258 (Fed. Cir. 1989). In construing the claims, the court should consider, if required, the claim language, the other claims, the prior art, the prosecution, and the specification. *S.R.I. Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1118 (Fed. Cir. 1985). "The determination of scope of the claims is a question of law, and [thus,] a dispute respecting that legal issue does not preclude summary judgment." *George v. Honda Motor Co., Ltd.*, 802 F.2d 432, 434 (Fed. Cir. 1986).

After the court has determined the proper meaning or interpretation of the patent claim itself, the next step is to apply the claims to the allegedly infringing device to determine whether that device falls within the scope of the claims. *C.R. Bard, Inc. v. Advanced Cardiovascular Systems, Inc.*, 911 F.2d 670, 673 (Fed. Cir. 1990). Where the facts underlying the alleged infringement are undisputed, it is the court's function to apply the claims to the accused device. *Martin v. Barber*, 755 F.2d 1564, 1567 (Fed. Cir. 1985) (citation omitted). If an accused product exhibits features [*7] corresponding to each of the elements set forth in any patent claim, then literal infringement exists. *Graver Tank*, 339 U.S. at 607.

a. Scope of the '468 Patent Claims

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The parties dispute whether the '468 patent claims only the testing strips, and thus is a "product" patent, or whether it is a "method" patent or "combination" patent of the strip and meter. This is an issue of law to be determined by interpreting the claims of the patent.

The claims of the '486 patent are quoted below, as they appear in the patent itself.

What is claimed is:

1. A reagent test strip for use in an apparatus for determining the blood glucose concentration of a sample of whole blood, said apparatus comprising optical means for detecting intensity of light at wavelengths of about 635 nm and about 700 nm reflected from at least a portion of said strip by reading the reflectance of at least a portion of said strip;

said strip having a porous portion disposed near a distal end of said strip such that the porous portion generally registers with the optical means of the apparatus when the strip is retained by the apparatus during determination of said blood glucose concentration, said [*8] porous portion having a sample receiving surface for receiving a sample of whole blood and a testing surface, said porous portion further comprising reagent means for indicating the concentration of blood glucose in said whole blood sample in the presence of optically visible hemoglobin by creating a change in reflectance at said testing surface indicative of the concentration of glucose present in said sample, said reagent means comprising chemical reagents selected to produce said change dependent upon the glucose concentration wherein said chemical reagents comprise a dye precursor forming a chromophore indica-

tive of the concentration of glucose present in said sample, said chromophore absorbing light at about 635 nm but not to any significant extent at about 700 nm.

2. The strip of claim 1 wherein said dye precursor comprises 3-methyl-2-benzothiazoline hydrazone hydrochloride and 3-dimethylaminobenzoic acid.

3. The strip of claim 2 wherein the chemical reagents are at a pH of 3.8 to 5.

Claims 1-3, '468 Patent.

Most persuasive to the court on the issue of claim interpretation is the language of the three claims themselves. Claim 1 begins with the words "[a] [*9] reagent test strip" while Claims 2 and 3 refer to "the strip of claim 1." It is clear that each claim constitutes a description of the claimed strip, not a claimed method. Each claim provides a detailed description of the makeup and qualities of the claimed strip, not of the method employed in testing blood glucose levels. Claim 1 repeatedly refers to the strip and its characteristics. Mention of the meter in which the strip is used serves to describe certain strip features, not to describe a combination of strip and meter. The mention of the meter apparatus in the first sentence of claim 1 serves to identify the environment in which the strip will be used, not to create a claim to the method of determining glucose levels in blood or to the combination of strip and meter. See e.g., *Smith Corona Corp. v. Pelikan, Inc.*, 784 F. Supp. 452, 463 (M.D. Tenn. 1992), *aff'd*, 1 F.3d 1252 (Fed. Cir. 1993); see also *In re Stencel*, 828 F.2d 751, 754-55 (Fed. Cir. 1987).

In addition to the language of the claims, i.e. the repeated references to the strips described in claims 1 through 3, the court finds that the prosecution history favors a finding that the '468 patent is directed [*10] solely to the strips themselves. The '468 patent arose out of a continuation application which was amended to contain new claims directed to a "reagent strip." In June, 1993, these amended claims were amended again, but still directed to a "reagent test strip." Although this amendment, given the number Claim 55, described the apparatus in which it was to be used, the dependent claims added along with Claim 55 each begins with the phrase "the reagent test strip of claim 55 . . ." After considering the amendments of claims 55 through 59, the patent examiner stated that it was "the examiner's posi-

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tion that the claims are directed to a test strip." Additionally, the examiner referred twice more in that communication to "the claimed test strip." Thereafter, LifeScan submitted an amendment canceling prior claims and adding Claim 60 incorporating the limitations of Claim 55. During and after the submission of Claim 60, LifeScan did not dispute the examiner's interpretation of Claim 55 as referring to the strip itself. In addition, Claim 60 added a feature relating to the nature of the chemicals in the strip.

After an initial rejection by the patent examiner, LifeScan conducted an interview [*11] with the examiner, during which drafts of new claims 61 and 62 were discussed. The first of the new claims, which later became claim 1 of the '468 patent, was directed to "a reagent test strip for use in an apparatus for determining the blood glucose concentration in a sample of whole blood." The second new claim, which became claim 2 of the '468 patent, was directed to "the strip of" the first claim. Following the interview, LifeScan also submitted a new claim 63, later claim 3 of the '468 patent, which also was directed to "the strip" of the preceding claim. Claim 61, which was later allowed, contains fewer references to the nature of the apparatus in which the strip is to be used. The references to the apparatus, i.e. the meter, which do exist are merely descriptive of the environment of the intended use of the strip. See e.g. *In re Stencel*, 828 F.2d at 754-55; see also *Smith Corona*, 784 F. Supp. at 463-65. Based on the court's review of the language of the claims and the patent history, the court has determined that, as a matter of law, the '468 patent claims the testing strip and therefore a product, not a method or combination of method and product.

In addition, this [*12] court is not persuaded by Polymer's argument that the '468 patent claims are limited to the reagent strip when in place in the meter with a whole blood sample present thereon. This interpretation is simply not supported by the claim language or the claim prosecution.

The court also finds unpersuasive Polymer's arguments concerning the interpretation of claim 3 of the '468 patent, which reads as follows: "The strip of claim 2 wherein the chemical reagents are at a pH of 3.8 to 5." Based on the claim language and the prosecution history, the court finds that the claim language refers to the pH of the chemical reactants in the dry strip, rather than the "pH of all of the chemicals in the strip when it is placed in the meter and a sample of whole blood is applied thereto" as is argued by Polymer.

Finally, based upon the language of the claims and the claim prosecution, the court finds that the language in claim 1 requiring that the porous portion of the strip

comprise reagent means for indicating the concentration of blood glucose in said whole blood sample in the presence of optically visible hemoglobin by creating a change in reflectance at said testing surface indicative of [*13] the concentration of glucose present in said sample, . . .

does not limit the claim to a strip in which the only hemoglobin that can be optically sensed by the apparatus is that which is "in the red blood cells filtered out and held at the surface of the test strip."

Polymer argues that its strip does not meet the elements of claim 1 because hemoglobin not "in the red blood cells filtered out and held at the surface of the test strip" is optically visible. However, the court disagrees with Polymer's interpretation of the claim language. First, the court finds that there is no indication that the '468 patent claim 1 is limited to a strip in which the only optically visible hemoglobin is that which is in the red blood cells. On this point, the court notes that the patent expressly refers to "blood being analyzed [flowing] through the pores of the matrix" and to "blood . . . wetting the polyamide matrix without having an excess liquid penetrate the porous matrix to interfere with the reflectance reading on the opposite side of the matrix." This language indicates that the claim is not limited to hemoglobin inside red blood cells, but rather also encompasses "free" hemoglobin [*14] released into the remainder of the sample. Second, even if the claim were limited in the manner alleged by Polymer, Polymer has not asserted that the hemoglobin presence in red blood cells applied to First Choice strips is not "optically visible" to at least some extent by the LifeScan home-use blood glucose meter.

Therefore, after reviewing the claim language, the patent specification, the prosecution history, the expert deposition testimony submitted, and the prior art, the court has determined that the proper meaning or interpretation of the '468 patent is that it is directed to the test strips per se, rather than to a method or combination of strip and meter. Additionally, the '468 patent claims refer to the strips themselves and are not limited to the strips when in the apparatus, with whole blood upon them. Finally, the phrase "in the presence of optically visible hemoglobin" does not limit claim 1 to a strip in which the only hemoglobin optically visible is that which is in red blood cells filtered out and held at the surface of the test strip.

b. Application of the Claims to Polymer's Test Strip

As noted above, the court has determined that the proper interpretation [*15] of the patent claim is that the '468 patent is directed to the test strip itself, not the method of testing blood glucose or the combination of the meter and strip. Now the court must apply the patent claims to Polymer's strips, called First Choice test strips, to determine whether the First Choice strips fall within the scope of the '468 patent claims. See *C.R. Bard, Inc. v. Advanced Cardiovascular Systems, Inc.*, 911 F.2d 670, 673 (Fed. Cir. 1990). As noted above, if an accused product exhibits features corresponding to each of the elements set forth in any patent claim, then literal infringement exists. *Graver Tank*, 339 U.S. at 607.

i. Alleged Disputes of Fact

LifeScan alleges that there is no genuine dispute of material fact concerning the features of the First Choice strips and of the strip claimed in the '468 patent. Polymer alleges that disputes of fact preclude summary judgment on the issue of whether each element of the '468 claims is found in the First Choice strips. The court addresses each of Polymer's factual contentions in turn.

First, Polymer argues that there is a dispute of fact as to whether its First Choice strip functions "just as described in the [*16] '468 patent." However, in support of its contention that the "First Choice strip in use functions in a substantially different manner from the strip disclosed and claimed in the '468 patent," Polymer simply refers to the declarations of two of its witnesses, an attorney, Gerald Bjorge, and Dr. Callis. This general assertion is insufficient to raise a genuine issue of fact in response to the specific facts submitted in support of LifeScan's motion. In addition, the court has reviewed the cited declarations and finds that they do not support Polymer's assertion of a dispute of fact on this issue, but instead contain disputes as to the legal interpretation of the claim language.

Second, Polymer alleges that there is a dispute of fact as to the pH level of the chemical reagents in its strips. As the court found above, the patent claims a strip with a Ph level of 3.8 to 5. As discussed above, Polymer has disputed the claim interpretation, but has not presented evidence disputing LifeScan's statement that "LifeScan's testing of the First Choice strips indicates that the strips are coated at a Ph within the range." Finally, at oral argument Polymer did not dispute that its own scientist, [*17] Dr. Gleisner, indicated during his deposition that Polymer's strips have a pH level of 4.4 when dry. Thus, the pH level of the First Choice strips falls within the 3.8 to 5 pH range specified in claim 3 of the '468 patent.

Finally, Polymer asserts that there is a factual dispute concerning whether hemoglobin in the red blood cells which is filtered out and held at the surface of the

test strip is visible to the optics of the meter apparatus. However, as the court discussed above, the claim is not limited to this interpretation and therefore, Polymer's arguments do not create a material dispute of fact. Rather, Polymer's assertion that its First Choice strip "has substantial free hemoglobin permeating through the porous portion of the strip" places the strip within the claim as interpreted by the court.

Thus, based on the foregoing, the court finds that there is no genuine dispute of material fact precluding summary judgment on the issue of literal infringement of the '468 claims.

ii. Elements of the '468 Patent Claims

LifeScan has presented undisputed evidence that all of the elements of the claims of the '468 patent are found in the First Choice strips made by Polymer. The [*18] court has reviewed the evidence submitted by the parties and compared it to the claim language. Each element of the three claims is found in the First Choice strips. The court finds that there is no limitation on the '468 claims requiring the strip to be in place in the blood-glucose monitoring apparatus with a sample of whole blood placed on it. Nor is there a limitation requiring that the "optically visible hemoglobin" be found only in red blood cells held at the surface of the testing strip. Finally, the pH levels of the First Choice strips fall within the range specified in claim 3.

Because each element of the claims of the '468 patent is found in the First Choice strip manufactured and sold by Polymer, the court finds that LifeScan has met its burden on summary judgment. Therefore, LifeScan's motion for summary judgment of literal infringement of the '468 patent is hereby GRANTED.

2. LifeScan's Motion for Summary Judgment of No Implied License Under the '468 Patent

LifeScan sells One Touch meters for home-use blood-glucose monitoring and also sells One Touch testing strips for use in taking blood glucose measurements. LifeScan claims patents on the meters per se, [*19] (U.S. Patent No. 5,059,394); on the strips per se, (the '468 patent); n1 and on the methods of making the blood glucose determinations when a testing strip, such as the First Choice or the One Touch strip, is used with a One Touch meter, (the '346 and '487 patents referred to previously in this order). As an affirmative defense to LifeScan's allegations of infringement of the '468 patent, Polymer has asserted that purchasers of LifeScan's One Touch meters are impliedly licensed to use Polymer's First Choice strip and that therefore, Polymer cannot be liable for infringement of the '468 strip patent.

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n1 The court has determined above that the '468 patent refers to the "reagent test strip" itself and is not a method or combination patent.

monopoly with respect to the article sold.

...

LifeScan moves for summary judgment of no implied license under the '468 patent, n2 asserting that the implied license argument is available to Polymer only if the '468 patent is a method or combination patent, as opposed to a product patent. Therefore, if the court determines, [*20] as it has above, that the '468 patent is a product patent, LifeScan argues that Polymer cannot raise the defense of implied license. The court agrees that the implied license doctrine is limited to method or combination patents and notes that Polymer has cited no case to the contrary. However, because Polymer expends great effort arguing that an implied license held by the consumers could create a defense to its own infringement liability, the court addresses the argument below.

Id. at 249 (citations omitted).

The parties in this matter cite two Federal Circuit cases which have also addressed the implied license doctrine, *Met-Coil Systems Corp. v. Korners Unlimited, Inc.*, 803 F.2d 684, 686-87 (Fed. Cir. 1986) and *Bandag, Inc. v. Al Bolser's Tire Stores, Inc.*, 750 [*22] F.2d 903, 925 (Fed. Cir. 1984). In *Bandag*, the owner of a patent claiming a method for retreading tires, *Bandag, Inc.*, sued *Al Bolser Tire Stores, Inc.* for infringing its patented method of retreading tires by using *Bandag* equipment which performed the patented methods. *Bolser* had purchased the equipment from a terminated *Bandag* franchisee, but was not licensed by *Bandag* to use it to perform the patented methods. *Bolser* argued that because *Bandag* did not prevent the sale of the equipment to a non-franchisee, and because the equipment would need to be modified in order to be used for a non-infringing purpose, that *Bolser* had acquired an implied license to use the equipment to practice the patented method. *Bandag*, 750 F.2d at 906-07, 924. However, the Federal Circuit Court of Appeals rejected those arguments, stating that "no license can be implied, where as here, the equipment involved has other noninfringing uses, even if only as replacement parts," *id.* at 924 (citation omitted), and that "[a] mere sale does not import a license except where the circumstances plainly indicate that the grant of a license should be inferred." *Id.* at 925 (citation omitted).

n2 LifeScan's motion for summary judgment of no implied license is directed to the '468 patent only. The issue of implied license with respect to the method patents, '346 and '487, is addressed in the motion by Polymer concerning non-infringement of the two method patents.

In the second [*23] case cited by the parties, *Met-Coil*, the Federal Circuit addressed whether "a patent owner's unrestricted sale of a machine useful only in practicing the claimed inventions presumptively carried with it an implied license under the patent." *Met-Coil*, 803 F.2d at 685. On the facts of that case, the Federal Circuit court held that the "patent owner's unrestricted sales of a machine useful only in performing the claimed process and producing the claimed product 'plainly indicate that the grant of a license should be inferred.'" *Id.* at 687. Therefore, the court held that "absent any circumstances tending to show the contrary," the sale of the machine gave *Met-Coil*'s customers "an implied license to practice the inventions claimed in *Met-Coil*'s patent." *Id.*

a. The Doctrine of Implied License

The doctrine of implied license was described in *United States v. Univis Lens Co.*, 316 U.S. 241, 249-51, 86 L. Ed. 1408, 62 S. Ct. 1088 (1942). In that case, the patent at issue covered multifocal eyeglass lenses. The [*21] patent owner sold blank lenses to its licensees. The Court held that when the licensees purchased the blank lenses, they acquired an implied license to complete the lenses through grinding and polishing, thereby practicing the final stage of the patented process. The Court stated that:

... it is plain that where the sale of the blank is by the patentee or his licensee -- here the Lens Company -- to a finisher, the only use to which it could be put and the only object of the sale is to enable the latter to grind and polish it for use as a lens by the prospective wearer. An incident to the purchase of any article, whether patented or unpatented, is the right to use and sell it, and upon familiar principles the authorized sale of an article which is capable of use only in practicing the patent is a relinquishment of the patent

Finally, the burden of proving the existence of an implied license is on the accused infringer. *Id.*

b. Application of the Implied License Doctrine

It is evident that there can be no implied license in this case, even utilizing the analysis in the "method" cases. First, Polymer has failed to show that there are no

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noninfringing uses for the test strip claimed in the '468 patent. n3 In fact, Polymer itself [*24] alleges that its own use of the test strips in setting calibration codes for its strips is a non-infringing use. Second, the circumstances of LifeScan's sale of its meters and test strips do not "plainly indicate that the grant of a license" to Polymer to make and sell the patented test strips "should be inferred." *Bandag*, 750 F.2d at 925. Finally, the court finds that whether or not LifeScan's customers have an implied license to practice the methods claimed in the two method patents, the '346 and '487, such a license does not create an implied license for Polymer to make and sell the test strips claimed in the '468 patent. n4 Polymer's argument that the consumers' alleged right to practice the method patents would be meaningless unless Polymer was granted a corresponding right to make and sell another patented product is frivolous as best.

n3 Polymer argues that there are no substantial noninfringing uses for the strip other than to practice the method patents. LifeScan argues that the standard is whether there are any nonfringing uses and alleges that there are indeed noninfringing uses for the meters, including using the meter to measure glucose in substances other than blood.

[*25]

n4 LifeScan alleges infringement of the '468 patent not simply due to the use of the test strip by the consumer meter-users, but due to Polymer's activities, pursuant to 35 U.S.C. Sec. 271(a) which states that "except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent." 35 U.S.C. Sec. 271(a) (emphasis added).

Therefore, LifeScan's motion for summary judgment of no implied license under the '468 patent is GRANTED.

3. Polymer's Motion for Summary Judgment of Invalidity of the '468 Patent Pursuant to 35 U.S.C. Sec. 112

Polymer moves for summary judgment of invalidity of the '468 patent pursuant to 35 U.S.C. Sec. 112, which provides that the patent

specification shall contain a written description of the invention, and of the

manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make [*26] and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Sec. 112, Para. 1. Sec. 112 also requires that the specification "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. Sec. 112, Para. 2.

According to the Federal Circuit, the Sec. 112, Paragraph 1 "written description" requirement exists to "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, [the applicant] was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991) (emphasis in original). Sec. 112, Paragraph 2 requires the claims to have a "clear and definite meaning when construed in the light of the complete patent document." *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985). The test for definiteness under Sec. 112, para. 2 is "whether those skilled in the art would understand what is claimed when the claim is read in light of the [*27] specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986). Compliance with the "written description" requirement of Paragraph 1 of Sec. 112 is a question of fact. *Vas-Cath*, 935 F.2d at 1563. "The description must clearly allow persons of ordinary skill in the art to recognize what is claimed." Id.

The presumption of validity of a U.S. patent, established by 35 U.S.C. Sec. 282, "requires that the party challenging validity prove the facts establishing invalidity by clear and convincing evidence." *Verdegaal Bros., Inc. v. Union Oil Co. of Calif.*, 814 F.2d 628, 631 (Fed. Cir. 1987) (citing *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir.), cert. denied, 469 U.S. 821, 83 L. Ed. 2d 41, 105 S. Ct. 95 (1984).

In support of its motion, Polymer has alleged numerous deficiencies in the patent specification, the textual description portion of the patent, and a lack of definiteness in the claims which define the "metes and bounds" of the invention. Polymer alleges that the specification does not describe what is meant by the words "in the presence of optically visible hemoglobin;" the specification [*28] does not describe that red blood cells from the whole blood sample pass into the pores of the matrix; the specification does not define the term "hematocrit" as

meaning "hemoglobin;" as well as other alleged deficiencies in the specification and the claim language.

Polymer has failed to present any evidence on the issue of how one skilled in the art would understand the language of the specification or the claims of the '468 patent. Instead, Polymer relies on its claim that Dr. Smith is not credible and argues that the indefiniteness and lack of clarity in the specification and claim language is clear on the face of the patent and that the court should, as a matter of law, determine that the patent fails to meet the Sec. 112 requirements.

LifeScan has, with the declaration of Dr. John Smith, LifeScan's Vice President of Research and Engineering, presented factual evidence that one skilled in the art would understand the '468 patent specification and that the specification and claim language is sufficiently clear and definite to meet the requirements of Sec. 112. Additionally, LifeScan has presented evidence, through Dr. Smith, that one skilled in the art would understand the metes [*29] and bounds of the claims when read in light of the specification. The court finds Polymer's arguments that Dr. Smith is not credible to be insufficient to overcome LifeScan's presentation of genuine disputes of material fact with respect to this motion. Because the court is unable to say, as a matter of law, that the claim and specification language fails to sufficiently describe the invention claimed, Polymer's motion for summary judgment of invalidity of the '468 patent pursuant to 35 U.S.C. Sec. 112 is hereby DENIED.

4. Polymer's Motion for Summary Judgment of Invalidity of the '468 Patent Under 35 U.S.C. Secs. 102(b) and 103

Polymer moves for summary judgment, arguing that the '468 patent is invalid because claims 1 and 2 of the patent are "anticipated," and claims 2 and 3 are "obvious," in light of prior art. As noted above, the presumption of validity of a United States patent, established by 35 U.S.C. Sec. 282, "requires that the party challenging validity prove the facts establishing invalidity by clear and convincing evidence." *Verdegaal Bros.*, 814 F.2d at 631 (citation omitted).

a. The Law of Anticipation

The law of anticipation is found in 35 U.S.C. [*30] Sec. 102(b). Pursuant to that statute, "[a] person shall be entitled to a patent unless . . . (b) the invention was patented or described in a printed publication in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States," 35 U.S.C. Sec. 102(b). A patent claim is anticipated "only if each and every element as set forth in the claim is found, either expressly or inherently described, in a

single prior art reference." *Verdegaal Bros.*, 814 F.2d at 631 (citation omitted).

b. The Law of Obviousness

The law of obviousness is found in 35 U.S.C. Sec. 103, which reads as follows:

[a] patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S.C. Sec. 103. To determine whether an invention would have been obvious at the time it was made, the court [*31] must "determine the scope and content of the prior art;" "ascertain the differences between the prior art and the claims at issue;" and "resolve the level of ordinary skill in the pertinent art." *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 716 (Fed. Cir. 1991), (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966)). In addition, secondary considerations such as "commercial success," "long felt but unsolved needs," and "failure of others to invent," "are also relevant to the obviousness inquiry." *Ryko*, 950 F.2d at 716, (citing *Graham*, 383 U.S. at 17-18).

c. Application to the Facts

Polymer alleges that the '468 patent is invalid because each element of claim 1 is anticipated in European patent application no. 0 140 337 by Dappen (the "Dappen" reference) and in European patent application no. 0 110 173 by LifeScan, Inc. (the "EP '173" reference). Polymer also argues that each element of claim 2 of the '468 patent is anticipated by EP '173. Finally, Polymer alleges that claims 2 and 3 would have been obvious; claim 2 from Dappen combined with the teachings of Ngo, et al. (found at 105 Anal. Biochem. 389-97 (1980)) which allegedly [*32] makes the dye couple system of the '468 obvious; and claim 3 from the teachings of Dappen combined with Geoghegan, et al. (found at 60 J. Immuno. Methods 61-68 (1983)) which allegedly would have made the pH range of claim 3 obvious.

In response to Polymer's motion, LifeScan has presented numerous issues of disputed fact underlying the determination of whether the '468 patent claims were anticipated or rendered obvious by prior art. In support of its opposition, LifeScan has submitted the declaration

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of Dr. Smith, who provides evidence of how one skilled in the art would interpret various aspects of the prior art references as well as the '468 patent. Polymer responds that there is not a dispute of material fact because LifeScan's arguments concern irrelevant issues of fact. Polymer additionally asserts that the court should discount Dr. Smith's testimony and therefore LifeScan's reliance on his testimony. The court will not, on summary judgment, determine the issue of credibility of witnesses. Dr. Smith testified that he was not skilled in the art of the legal interpretation of patent claims, as he is "a scientist, not a lawyer." That testimony does not in any way preclude LifeScan's [*33] reliance on Dr. Smith for matters beyond "the legal interpretation of patent claims" including how one skilled in the relevant scientific field would understand the prior art references.

Based on the evidence presented by LifeScan and Polymer, the court finds that there exist genuine disputes of material fact concerning what may be anticipated by, and what may be rendered obvious by, the teachings of the prior art references. These include, but are not limited to, the following: whether one skilled in the art would understand Dappen's "registration layer" to be "porous;" whether the absorbance characteristics of Dappen's dyes are "inherently" those required by the '468 patent claims; whether the greater rate of absorption of light by the Dappen dye system meets the requirement of the '468 patent claims that it not absorb light "to any significant extent at about 700 nm;" whether it is obvious from Dappen or Geoghegan that the dye precursors in Geoghegan should be substituted for those in Dappen; and whether it would be obvious that the appropriate pH level is from 3.8 to 5.

Finally, in addition to the above disputed facts, the court finds that the evidence of so-called "secondary" [*34] considerations such as commercial success, long felt but unsolved needs, and failure of others to invent, weighs heavily in favor of LifeScan on the issue of obviousness.

Based on the foregoing, the court concludes that there are genuine disputes of material fact precluding summary judgment on the issues of anticipation and obviousness and therefore Polymer's motion for summary judgment under 35 U.S.C. Secs. 102(b) and 103 is DENIED.

C. The '346 and '487 Patents

The following motions relate to both the '346 and the '487 patents: LifeScan's Motion for Summary Judgment of Literal Infringement of the '346 and '487 Patents and Polymer's Motion for Summary Judgment of Non-Infringement of the '346 and '487 Patents.

1. LifeScan's Motion for Summary Judgment of Literal Infringement of the '346 and '487 Patents

LifeScan alleges that Polymer literally infringes various claims of the '346 and '487 patents. By statute, "whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent." 35 U.S.C. Sec. 271(a). In addition, "whoever actively induces infringement of a patent shall be liable [*35] as an infringer." 35 U.S.C. 271(b). Finally,

whoever sells a . . . material . . . for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

35 U.S.C. 271(c). LifeScan has the burden of proving infringement by a preponderance of the evidence. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1054 (Fed. Cir.), cert. denied, 488 U.S. 825, 102 L. Ed. 2d 51, 109 S. Ct. 75 (1988).

As set out above in Section II.B.1, to determine whether or not a patent has been literally infringed, the court follows a two-step process. First, the court must ascertain the proper meaning or interpretation of the patent claim itself. *Autogiro Co. of Amer. v. U.S.*, 181 Ct. Cl. 55, 384 F.2d 391, 401 (Ct. Cl. 1967); see also *Corning Glass Works v. Sumitomo Electric U.S.A., Inc.*, 868 F.2d 1251, 1258 (Fed. Cir. 1989). In construing the claims, the court should consider, if required, the claim language, the other [*36] claims, the prior art, the prosecution, and the specification. *S.R.I. Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1118 (Fed. Cir. 1985).

After the court has determined the proper meaning or interpretation of the patent claims themselves, the next step is to apply the claims to the allegedly infringing device to determine whether that device falls within the scope of the claims. *C.R. Bard, Inc. v. Advanced Cardiovascular Systems, Inc.*, 911 F.2d 670, 673 (Fed. Cir. 1990). If an accused product exhibits features corresponding to each of the elements set forth in any patent claim, then literal infringement exists. *Graver Tank*, 339 U.S. at 607.

LifeScan alleges that Polymer literally infringes, or induces its customers to infringe, at least claims 1-3, 6-8, and 10-18 of the '346 patent, which are set forth in Ap-

pendix A of this order. LifeScan also alleges that Polymer has literally infringed claims 1 and 2 of the '487 patent, which are set forth in Appendix B of this order.

In response to LifeScan's motion, Polymer alleges that there are disputes of fact which preclude summary judgment of literal infringement of the '346 and '487 patents. However, most of the alleged [*37] factual disputes are actually disputes about the legal interpretation of the claim language.

The parties dispute whether Polymer's First Choice strip, and the LifeScan One Touch strip, are composed of single-layer membranes or multi-layered membranes. This court finds that this is not a factual dispute, as the parties agree that the strips are made in the same manner, but rather is a semantic disagreement over the characterization of the resulting strip and the legal meaning of the phrase "single-layer membrane" as used in claims 1, 10 and 15. The strips are created by a technique taught in the patents which consists of "casting the hydrophilic polymer onto a core of non-woven fibers." The court finds that the resulting membrane, having been cast on a non-woven support, is single-layer. It is undisputed that both strips are formed in this manner. Therefore, the court finds that Polymer's First Choice strips fall within the language of claims 1, 10, and 15.

The parties also dispute the meaning of the phrases "filters out red blood cells" and "exclude red blood cells" found in claims 1, 10, and 15. The court finds that the phrases, properly interpreted, do not require the porous membrane [*38] to prevent absolutely all red blood cells from entering the membrane. It is undisputed that both strips do "filter[] out" and "exclude" red blood cells.

The remaining issues raised by Polymer in its opposition to LifeScan's motion of literal infringement all purport to be factual disputes. However, the court has reviewed Polymer's statement of disputed facts and finds that all but two of the issues raised by Polymer are legal arguments as to the meaning of the claims or semantic disputes concerning the description of First Choice strips, which do not actually raise any factual issues themselves. The two exceptions are Polymer's statement that the dye product in the First Choice strips absorbs light at the same wavelength that red blood cells absorb light and Polymer's contention that its use of the strips does not involve the practice of the patented methods. However, as to the issue of the rate of light absorption, Polymer's only attempt to create a genuine factual dispute has been to present unsubstantiated affidavit evidence which contradicts the prior sworn testimony of another of Polymer's own witnesses on this issue, without any explanation of the discrepancy. At oral argument, [*39] Polymer's counsel did not deny that its expert Dr. Callis had previously testified that the dye prod-

uct does absorb light at a different wavelength than does red blood cells, nor did Polymer's counsel contend that Dr. Callis had been mistaken when he testified concerning his conclusions after conducting a scientific examination. The court finds that Polymer has failed to create a genuine factual dispute on this issue.

As to the second allegedly disputed factual issue, concerning Polymer's use of the strips in a manner which actually practices the patented methods, the court finds that Polymer has failed to rebut the factual assertions by LifeScan that Polymer's use of the meters, whether to demonstrate them, or for clinical testing, would constitute practice of the claimed methods. At oral argument, Polymer's counsel failed to deny that Polymer has used the meters to practice the claimed methods. Instead, in Polymer's statement of disputed facts, Polymer focuses on arguing that using the meters to set calibration codes for its strips would not be an infringing use because the meter is not being used to test the amount of glucose, which is already known during the procedure. Whether [*40] or not the use of the meter to set the calibration code on the strips constitutes practicing the claimed patented methods, Polymer notably fails to deny that it has used the meters to measure glucose.

Finally, Polymer questions whether LifeScan has presented sufficient evidence showing that the meter, when used, actually practices the claimed methods. The court finds that, through Dr. Smith's testimony, LifeScan has put forth sufficient evidence that use of the meters to measure blood glucose does practice the claimed methods and therefore Polymer must come forth with counter-evidence demonstrating that there are genuine issues of material fact on the issue. See *Scripps Clinic & Res. Fdn. v. Genentech, Inc.*, 927 F.2d 1565, 1571 (Fed. Cir. 1991) (citations omitted). Polymer has not done so. Therefore, the court finds that there is no genuine dispute of material fact concerning whether the meter actually practices the claimed methods, and therefore whether Polymer's use of it thereby infringes the method patents.

In addition, Polymer has failed to rebut the evidence offered by LifeScan that use of the First Choice strips in the meters, when measuring blood glucose levels, infringes [*41] claims 1-3, 6-8, and 10-18 of the '346 patent and claims 1 and 2 of the '487 patent, as those claims have been interpreted by the court. Based on this analysis, the court GRANTS LifeScan's motion for summary judgment of literal infringement of claims 1-3, 6-8, and 10-18 of the '346 patent and claims 1 and 2 of the '487 patent.

The court notes that Polymer has again raised the possibility that the customers purchasing the First Choice strips may have an implied license to practice the methods claimed. However, at this stage, the court is merely

determining infringement by Polymer of the claimed methods, not any possible defenses to that infringement. The court has, in this order, denied summary judgment to Polymer on the issue of whether the consumer purchasers of the One Touch meters have been granted an unrestricted implied license to practice the claimed methods because disputed factual issues exist.

2. Polymer's Motion for Summary Judgment of Non-Infringement of the '346 and '487 Patents

Polymer has moved for summary judgment of non-infringement of the '346 and '487 method patents on the basis of the following argument: only the consumer users of the One Touch meters [*42] can directly infringe the method patents (the '346 and the '487) because only they practice the claimed methods; the consumers have an implied license to use the meters in their intended fashion; consumers additionally are impliedly licensed to use the meters with First Choice test strips because either the consumer bought a meter without a sticker cautioning the buyer about patent infringement or because the consumer purchased a meter with a warning sticker but the stickers are ineffective as a matter of law. Polymer additionally argues that because the consumers are allegedly impliedly licensed to use the meters with First Choice strips, there is no direct infringement and therefore Polymer cannot be derivatively liable for inducing or contributory infringement. Finally, Polymer claims it does not practice the method patents itself, and therefore cannot be directly liable for infringement of the method patents.

As set out in detail above, in section II.B.2. of this order, an implied license will only be found when there is no non-infringing use for the article sold (i.e., the only use for the article is one that carries out a patented method or completes a patented combination) [*43] and the circumstances of the sale plainly indicate that the grant of a license should be inferred. *Met-Coil Systems Corp. v. Korners Unlimited, Inc.*, 803 F.2d 684, 686-87 (Fed. Cir. 1986); *Bandag, Inc. v. Al Bolser's Tire Stores, Inc.*, 750 F.2d 903, 925 (Fed. Cir. 1984). The burden of proving the existence of an implied license is on the accused infringer. *Met-Coil*, 803 F.2d at 687.

The court cannot grant summary judgment on this motion. LifeScan has presented evidence creating a genuine dispute of fact concerning whether there are non-infringing uses for the One Touch meters. Under *Bandag*, an implied license does not exist if there are non-infringing uses. *Bandag*, 750 F.2d at 924 ("no license can be implied, where as here, the equipment involved has other noninfringing uses, even if only as replacement parts").

In addition, even if there were no disputes of fact on the issue of non-infringing uses, this court cannot say as

a matter of law, on the evidence presented by Polymer, that the circumstances of the sales "plainly indicate that the grant of a license should be inferred." *Met-Coil*, 803 F.2d at 687. The '346 patent issued in June, 1990 and the '487 patent [*44] in September, 1991. LifeScan's '468 patent was issued on April 19, 1994. Under United States patent law, a patent owner has no enforceable rights under a patent until the patent issues. *Marsh v. Nichols, Shepard & Co.*, 128 U.S. 605, 612, 32 L. Ed. 538, 9 S. Ct. 168 (1888). LifeScan has presented a genuine issue of material fact as to what expectation customers could have had concerning a license to use a then non-existent patent. Additionally, Polymer has brought forward no evidence of the grant of such an implied license except for the actual sales of the meters, some sold with and some without caution stickers. Notably, no test strips other than LifeScan's strips were authorized by the FDA to be marketed for use with the One Touch meter at that time. Additionally, LifeScan has presented evidence of customer literature included in its meter packaging which creates a factual issue concerning the circumstances surrounding the sales of the meters.

With respect to meters sold at later dates, LifeScan has similarly raised genuine disputes of material fact. No strips other than LifeScan's own strips were available for use with One Touch meters prior to the time at which LifeScan began [*45] placing stickers cautioning purchasers about patent infringement possibilities. In addition, LifeScan continued placing information in its packaging which creates a dispute of fact concerning the circumstances of the sales and is evidence precluding a finding of an implied license. Finally, Polymer has failed to convince the court that the caution sticker placed on the LifeScan One Touch meters beginning in April, 1993 is ineffectual, as a matter of law, to restrict the use of the meter. At the very least, the sticker language creates a dispute of fact concerning the expectations of a reasonable customer and whether the circumstances of the sales "plainly indicate that the grant of a license should be inferred." *Met-Coil*, 803 F.2d at 687.

Because this court finds that LifeScan has raised genuine disputed issues of material fact in opposition to the motion, Polymer's motion for summary judgment of non-infringement of the '346 and '487 patents is DENIED.

D. LifeScan's Motion for Summary Judgment of No Misuse with Respect to All Three Patents

LifeScan has moved for summary judgment on the issue of whether or not there was misuse of the three patents at issue in this case, [*46] the '468, the '346 and the '487. Polymer has asserted misuse of the patents as a defense to liability. Patent misuse as a defense refers to inequitable conduct engaged in by the patent owner

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which renders the patent unenforceable. *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 493-94, 86 L. Ed. 363, 62 S. Ct. 402 (1942). 35 U.S.C. Sec. 271(d), enacted in 1952, codified the doctrine of contributory infringement and addressed the issue of patent misuse as follows:

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following:

(1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent;

(2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent;

(3) sought to enforce his patent rights against infringement or contributory infringement.

35 U.S.C. Sec. 271(d).

The Supreme Court interpreted [*47] Sec. 271(d) in *Dawson v. Rohm & Haas Co.*, 448 U.S. 176, 65 L. Ed. 2d 696, 100 S. Ct. 2601 (1980). In *Dawson* the court held that "the provisions of Sec. 271(d) effectively confer upon the patentee, as a lawful adjunct of his patent rights, a limited power to exclude others from competition in nonstaple goods. A patentee may sell a nonstaple article himself while enjoining others from marketing the same good without his authorization." *Id.* at 201. A nonstaple article is "one which was designed to carry out the patented process and has little or no utility outside of the patented process." *Polysius Corp. v. Fuller Co.*, 709 F. Supp. 560, 576 (E.D. Pa. 1989). Polymer has presented no evidence disputing LifeScan's claim that the test strips designed for use with LifeScan's One Touch meters are nonstaple items. n5 The court finds that the blood glucose test strips are nonstaple items.

n5 Polymer's claims that the meter purchasers are impliedly licensed to use other brands of strips does not create a substantial non-infringing use, rather it would provide the infringing consumer with an implied license defense to infringement liability. See generally, *Dawson*, 448 U.S. 176, 65 L. Ed. 2d 696, 100 S. Ct. 2601 (1980).

[*48]

The court notes that in *Dawson* the patentee was permitted to limit competition in the sale of an unpatented staple item, whereas here the strip itself is patented, thus making this an even stronger case in favor of a finding of no misuse.

The court is not persuaded by Polymer's arguments that the holding in *Dawson* has been restricted by the enactment of the Patent Misuse Reform Act of 1988, codified at 35 U.S.C. 271(d)(4)-(5). n6 It is clear from the legislative history that Congress intended to extend, not limit, the protection provided by *Dawson*. See 134 Cong.Rec. S17146-48 (Oct. 21, 1988) (Amendments enacted to "support [the] enhancement of intellectual property rights" and to "deter misuse claims that unnecessarily burden infringement litigation"). Since the 1988 amendments courts have continued to interpret *Dawson* as this court does here. See e.g., *Joy Technologies Inc. v. Flakt, Inc.*, 1992 U.S. Dist. LEXIS 21720, *8, 24 U.S.P.Q.2d 1150, 1152 (D.Del. 1992), vacated and remanded on other grounds, 6 F.3d 770 (Fed. Cir. 1993); *Alcon Laboratories Inc. v. Allergan Inc.*, 1990 U.S. Dist. LEXIS 13348, *43-44, 17 U.S.P.Q.2d 1365, 1377 (N.D. [*49] Tex. 1990); *Polysius*, 709 F. Supp. at 576.

n6 35 U.S.C. Secs. 271(d)(4) and (5) read as follows:

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following:

. . . (4) refused to license or use any rights to the patent; or

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(5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or the patented product on which the license or sale is conditioned.

As the court has found that blood glucose test strips are nonstaple items, the court holds that LifeScan has not misused the patents at issue. Therefore, the court hereby GRANTS LifeScan's motion for summary [*50] judgment of no misuse of the '468, the '346 and the '487 patents.

E. Polymer's Motion to Amend Answers

Pursuant to *Fed.R.Civ.P. 15(a)* Polymer as moved to amend its answers to the complaints filed in this matter. n7 Polymer requests leave to amend its answers in order to add specific allegations of inequitable conduct pleaded as an affirmative defense in this case.

n7 This matter results from the consolidation of two complaints. Polymer has filed two answers, one to each of the complaints.

Whether to permit a party to amend its pleading is a matter within the court's discretion. *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 330, 28 L. Ed. 2d 77, 91 S. Ct. 795 (1971). The court should consider whether allowing the proposed amendment will cause undue delay, whether it is in good faith, whether it will unduly prejudice the opposing party and whether the amendment may be futile. *Foman v. Davis*, 371 U.S. 178, 182, 9 L. Ed. 2d 222, 83 S. Ct. 227 (1962).

The court has considered [*51] the proposed amendments and has determined that if allowed, undue delay would result. The court is convinced that if amendment were permitted, the court would need to allow LifeScan additional discovery. The discovery period in this case had passed prior to Polymer's filing of its motion to amend. n8 Extensive discovery has already occurred and any further discovery permitted now would jeopardize the current trial date of January 30, 1995. In addition, the court believes that the amendments would cause the trial to be longer than the currently scheduled fifteen-day jury trial, which would cause additional

scheduling difficulties, thus delaying the eventual resolution of the entire case. The court also finds that LifeScan would be unduly prejudiced if it were required to interrupt its trial preparation to undertake discovery and/or file motions concerning the proposed amendments. The court notes that the October 13, 1994 deadline for filing dispositive motions passed the same day this motion was filed.

n8 The discovery period in this matter ended on October 4, 1994. Polymer filed the motion to amend its answers on October 13, 1994.

[*52]

LifeScan argues that Polymer's proposed amendments would also be futile and would not withstand a motion to dismiss. The court has not determined whether or not the amendments would be futile. The trial date in this matter is rapidly approaching and the court does not wish to divert the parties from their trial preparation by requiring an additional round of briefing on the legal sufficiency of the amendments. Finally, the court believes it would be improper to delay the trial in this matter any longer.

F. LifeScan's Motion for Preliminary Injunction

In this motion, LifeScan requests that Polymer be preliminarily enjoined from "manufacturing, using, or selling, or inducing others to manufacture, use, or sell, blood glucose test strips, including the First Choice test strips, for use with One Touch meters, and any other product which infringes LifeScan's United States Letters Patent No. 5,304,468." n9

n9 This motion comes before the court on remand from the Federal Circuit. The Federal Circuit vacated this court's June 9, 1994 order denying LifeScan's motion for a preliminary injunction. See *LifeScan v. Polymer*, 39 F.3d 1198 (Fed. Cir. Oct. 18, 1994). Because the initial order has been vacated, the court intends for this order to supersede the June 9, 1994 order.

[*53]

1. Legal Standard

Injunctive relief in patent cases is authorized pursuant to 35 U.S.C. Sec. 283 and under case law. See e.g., *Smith Int'l., Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1577-79 (Fed. Cir. 1983), cert. denied, 464 U.S. 996, 78 L. Ed. 2d 687, 104 S. Ct. 493 (1983). The Federal Circuit

has established the following test for determining whether to issue an injunction in patent matters:

... to obtain a preliminary injunction, pursuant to 35 U.S.C. Sec. 283, a party must establish a right thereto in light of four factors: (1) reasonable likelihood of success on the merits; (2) irreparable harm; (3) the balance of hardships tipping in its favor; and (4) the impact of the injunction on the public interest.

These factors, taken individually, are not dispositive; rather, the district court must weigh and measure each factor against the other factors and against the form and magnitude of the relief requested.

Hybritech Inc. v. Abbott Laboratories, 849 F.2d 1446, 1451 (Fed. Cir. 1988).

2. Discussion

Above, the court has determined that the '468 patent claims the blood glucose test strips themselves, and thus is a product patent, rather [*54] than a patent for a method or combination of method and product. The court also determined that Polymer has literally infringed the '468 patent and that LifeScan has not impliedly licensed Polymer under the '468 patent to make, use, or sell the blood glucose test strips. Additionally, the court found that LifeScan has not misused the '468 patent. Finally, the court found that it could not say, as a matter of law, that the '468 patent was invalid pursuant to 35 U.S.C. Sec. 112, for indefiniteness, or pursuant to 35 U.S.C. Secs. 102(b) and 103, for anticipation and obviousness.

a. Reasonable Likelihood of Success on the Merits

According to the Federal Circuit, in order to merit the granting of a preliminary injunction, "a patent holder must establish a likelihood of success on the merits both with respect to validity of its patent and with respect to infringement of its patent." *Hybritech*, 849 F.2d at 1451. As noted, the court has determined, as a matter of law, that Polymer has literally infringed the '468 patent. The court has also determined that LifeScan has not misused the '468 patent, or impliedly licensed Polymer to make, use or sell the blood glucose test strips [*55] claimed by the '468 patent. Accordingly, Polymer cannot assert those issues as defenses at trial. However, because the court has not determined whether or not the '468 is valid as a matter of law, n10 it remains for the court to consider the likelihood that LifeScan will prevail at trial on the validity issue.

n10 Finding the existence of genuine disputes of material fact, the court has denied Polymer's two motions for summary judgment of invalidity of the '468 patent.

The court has considered the various prior art references cited by Polymer in connection with Polymer's motion for summary judgment of invalidity of the '468 patent pursuant to 35 U.S.C. Secs. 102(b) and 103. Having considered this evidence, the court finds that there is a substantial likelihood that LifeScan will demonstrate at trial that the '468 patent claims are not disclosed in the prior art, and are not rendered obvious or anticipated by the prior art references. The court will not be the ultimate finder of fact on that issue; it will [*56] remain for the jury to determine. However, for purposes of the motion for a preliminary injunction, the court must weigh the evidence and thus it has considered whether the claims in the '468 patent would have been anticipated or obvious from the prior art references and concludes that LifeScan has made a strong showing that it will prevail on the issue.

Specifically, the court finds that the following differences alleged by LifeScan are likely to be persuasive to the jury on the issue of whether the strip is novel: most of the prior art relied upon by Polymer was considered by the Patent Examiner prior to his allowance of the '468 patent claims, in particular the court believes that there is persuasive evidence that the European Patent Application No. 0110173A ("the '173 patent") was considered by the Patent Examiner and found not to preclude the '468 claims; the court also finds that LifeScan has presented compelling evidence that the '173 patent does not disclose both a "sample receiving surface" and a "testing surface" and that the Przybylowicz and Clement patents concern "multi-layer strips" unlike the '468 single-layer strip; the Przybylowicz and Clement patents do not disclose [*57] a reading taken "in the presence of optically visible hemoglobin;" the Dappen reference does not appear to the court to disclose a porous portion as required by the '468 patent; the Dappen reference dye system does not appear to meet the '468 claim requirement that it not absorb light "to any significant extent at about 700 nm; it does not appear that Dappen or Geoghegan teach that the dye precursors in Geoghegan should be substituted for those in Dappen; it does not seem that the references cited by Polymer would make it obvious that the appropriate pH level is from 3.8 to 5, as required by claim 3 in the '468 patent. Thus, based on the court's view of the prior art evidence, LifeScan is likely to prevail on the issues of obviousness and anticipation.

In addition to the above findings concerning the prior art references, the court finds that LifeScan has made a showing of likelihood of success on the issue of validity by presenting considerable objective evidence of non-obviousness of the inventions claimed in the '468 patent. Specifically, the court finds that LifeScan has made a strong showing of the following evidence of non-obviousness: the inventions claimed in the '468 strip [*58] patent have enjoyed considerable commercial success; Polymer has experienced tremendous growth in sales of its One Touch strips which the court has found above infringe the '468 claims; the improvement in results for the users of the glucose monitoring system which was achieved with non-wipe strips is marked and has contributed to the commercial success; and finally, LifeScan has presented considerable evidence that Polymer developed its First Choice strips by following the '468 patent claims and disclosure. Based on the objective evidence presented by LifeScan on the issue of non-obviousness, the court finds that LifeScan has made a strong showing that it is likely to succeed on the issue of obviousness at trial.

Finally, the court finds that LifeScan is likely to prevail at trial on the issue of validity under 35 U.S.C. Sec. 112, which requires definiteness in the claim and specification language. Although the court found above that there remained disputed issues of fact, the court has considered the evidence presented by both sides on the issue and is of the opinion that LifeScan is more likely to prevail on the issue of whether, through the testimony of Dr. Smith, the '468 description [*59] would allow one skilled in the art to recognize what is claimed.

Therefore, the court finds that LifeScan has shown a likelihood of success on the merits of the issue of validity. As the court has already found that Polymer has infringed the '468 patent as a matter of law, LifeScan has "established a likelihood of success on the merits both with respect to validity of its patent and with respect to infringement of its patent." *Hybritech*, 849 F.2d at 1451.

b. Irreparable Harm

The court makes the following findings with respect to the issue of irreparable harm: LifeScan did not delay in seeking a preliminary injunction with respect to the infringement of the '468 patent as it filed its preliminary injunction motion (in an action in the Eastern District of Pennsylvania) on the same day the '468 patent issued, April 19, 1994; LifeScan's grant of a license to Can Am, another strip manufacturer, does not negate the possibility of irreparable harm caused by Polymer's actions; Polymer's sales have increased dramatically over the past eight months; Polymer has captured a substantial portion of the market in test strips over the past months; LifeScan is losing market share [*60] to Polymer; Polymer's

assets are insufficient, based upon the testimony of Polymer's chief financial officer Ms. Helenick, to satisfy the damages LifeScan will be able to claim if it prevails on the merits at trial; and LifeScan is likely to lose good will with its customers because of the pricing difference between One Touch and First Choice strips. Therefore, based on these findings, the court holds that LifeScan has demonstrated that it will suffer irreparable harm if Polymer is not enjoined.

c. The Balance of Hardships

The court finds that the balance of hardships tips in favor of LifeScan. LifeScan cannot recover from the irreparable harm outlined above even if it prevails at trial. Additionally, LifeScan has offered to post a bond sufficient to cover any potential damages suffered by Polymer due to an injunction. Although the court recognizes that Polymer and its employees will be harmed substantially by an injunction, it is persuaded that such harm is less than that which would be suffered by LifeScan if Polymer continued producing and selling the First Choice strips.

d. Impact on the Public Interest

The court finds that although there are advantages to [*61] the public in being able to purchase low-cost medical products, the public interest favors the granting of an injunction in favor of LifeScan. Congress has determined that "it is necessary to grant temporary monopolies on inventions in order to induce those skilled in the 'useful arts' to expend the time and money necessary to research and develop new products." *Eli Lilly & Co. v. Premo Pharmaceutical Labs., Inc.*, 630 F.2d 120, 137 (3d Cir.), cert. denied, 449 U.S. 1014, 66 L. Ed. 2d 473, 101 S. Ct. 573 (1980) (citations omitted). Congress has made the legislative determination that it is not in the public interest to permit the infringement of those temporary monopolies as it undermines inventor incentive.

e. Conclusion

Having balanced the relevant factors, and having considered all of the evidence presented by the parties, the court finds that LifeScan has demonstrated that it is entitled to a preliminary injunction prohibiting Polymer from "manufacturing, using, or selling, or inducing others to manufacture, use, or sell, blood glucose test strips, including the First Choice test strips, for use with One Touch meters. For security, pursuant to *Fed.R.Civ.P.* 65, [*62] LifeScan shall file with the Clerk of this court a surety bond in the amount of \$ 5,000,000. within five working days of this order.

III. CONCLUSION

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Based on the foregoing, the court hereby rules as follows:

1) the court GRANTS LifeScan's motion for summary judgment of literal infringement of the '468 patent;

2) the court GRANTS LifeScan's motion for summary judgment of no implied license under the '468 patent;

3) the court DENIES Polymer's motion for summary judgment of invalidity of the '468 patent pursuant to 35 U.S.C. Sec. 112;

4) the court DENIES Polymer's motion for summary judgment of invalidity of the '468 patent pursuant to 35 U.S.C. Secs. 102(b) and 103;

5) the court GRANTS LifeScan's motion for summary judgment of literal infringement of the '346 and '487 patents;

6) the court DENIES Polymer's motion for summary judgment of noninfringement of the '346 and the '487 patents;

7) the court GRANTS LifeScan's motion for summary judgment of no misuse of the '468 patent, the '346 patent, and the '487 patent;

8) the court DENIES Polymer's motion to amend its answers; and

9) the court GRANTS LifeScan's motion for a preliminary injunction concerning the '468 patent. [*63]

DATED at Seattle, Washington this 3rd day of January, 1995.

BARBARA J. ROTHSTEIN

UNITED STATES DISTRICT JUDGE

APPENDIX A

'346 Patent Claims 1-3, 6-8, and 10-18

1. In a method for determining glucose in a blood sample employing a membrane and a signal-producing system which reacts with glucose to produce a light-absorptive dye product, said system being bound to the membrane, and in which the amount of said dye product is determined by means of a reflectance measurement from a surface of said membrane, an improvement which comprises:

applying an unmeasured whole blood sample to a first

surface of a single-layer, substantially reflective, porous, hydrophilic membrane having pores of a size sufficient to ex-

clude red blood cells and which contains said signal-producing system;

making said reflectance measurement on a second

surface of said membrane other than the surface to which said sample is applied without removing excess sample or red blood cells from said first surface; and

determining the concentration of glucose in said sample

from said reflectance measurement.

2. A method according to claim 1, wherein said signal-producing system produces [*64] a dye product which absorbs light at a wavelength different from a wavelength at which said red blood cells absorb and said reflectance measurement is made at two different wavelengths, one absorption wavelength reflectance measurement to correct for background absorbance due to red blood cells and the other reflectance measurement at the absorption wavelength of said dye product.

3. A method according to claim 2, wherein said two wavelengths are at about 635 and 700 nm.

6. A method according to claim 1 wherein said membrane comprises polyamide and said signal producing system comprises glucose oxidase, peroxidase, and 3-methyl-2-benzothiazolinone hydrazone/3-(dimethylamino)benzoic acid.

7. The method of claim 1, wherein said pores have an average diameter of from about 0.1 to about 3.0 μm .

8. The method of claim 1, wherein said membrane consists essentially of polyamide and has a thickness of from about 0.01 to about 0.5 mm.

10. A method for determining glucose comprising the sequential steps of:

(a) applying a whole blood sample to an application site on a reagent element wherein said reagent element comprises a single-layer, substantially reflective, porous, hydrophilic [*65] matrix which filters out red blood cells and to which is bound a signal-producing system comprising glucose oxidase, peroxidase, and a dye indicator, which signal-producing system reacts with glucose to form a reaction dye product;

(b) allowing the sample to migrate to a reading site on said membrane different from said application site;

(c) monitoring reflectance at said reading site for a decrease in reflectance indicative of sample presence in said reading site in order to initiate timing of an incubation period;

and

(d) determining the change in reflectance at said reading site during the incubation period as a measure of dye product formed to determine the amount of glucose in said sample

wherein

all reflectance measurements at said reading site are performed without removing excess sample or red blood cells from said application site and at least one measurement is taken at a wavelength at which light is absorbed by said dye product.

11. A method according to claim 10, wherein said dye indicator is 3-methyl-2-benzothiazolinonehydrazone/3-(dimethyl-amino)benzoic acid.

12. A method according to claim 10, wherein said hydrophilic membrane comprises [*66] a polyamide.

13. A method according to claim 12, wherein said hydrophilic membrane is positively charged.

14. The method of claim 10, wherein said determination of the amount of glucose in said sample further includes determining the change in reflectance at a second wavelength to provide a correction for background absorbance at the dye product absorbing wavelength due to an interfering substance in said sample.

15. A method of determining analyte concentration in a liquid, which comprises:

quantitatively measuring baseline reflectance from a

first surface of a reagent element comprising an inert, porous, hydrophilic, substantially reflective, single-layer matrix having pores of a size sufficient to exclude red blood cells and a reagent system which interacts with said analyte to produce a light-absorbing reaction product, said reagent system being impregnated in

the pores of said matrix, prior to application of said liquid to said reagent element;

applying said liquid to a second surface of said

reagent element and allowing said liquid to migrate from said second surface to said first surface;

quantitatively measuring reaction reflectance from said

first [*67] surface of said reagent element without removing excess sample or non-migrating components of said sample from said second surface;

quantitatively measuring reflectance of interfering

substances from said first surface of said reagent element using a wavelength of light reflected by interfering substances and different from the wavelength of light used to measure said reaction product reflectance in order to correct for background reflectance at the reaction product wavelength caused by interfering substances; and

calculating a value expressing said analyte

concentration from said reflectance measurements.

16. The method of claim 15, wherein said matrix comprises a polyamide.

17. The method of claim 15, wherein the average diameter of the pores in said matrix is from 0.2 to 1.0 μm and said liquid is whole blood.

18. The method of claim 17, wherein said analyte is glucose, and said reagent produces a light-absorbing reaction product upon reacting with glucose.

APPENDIX B

Claims 1 and 2 of the '487 Patent

1. A method of causing an analytical measurement to be made in a reflectance-reading device at the end of a predetermined time period after an analyte [*68] reacts with a reagent in a porous, reflectance-reading matrix located in said device, which comprises:

taking a first reflectance reading from a dry first

surface of said porous matrix prior to application of a sample of body fluid suspected of containing said analyte to a sec-

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ond surface of said porous matrix from which said sample can travel to said first surface by capillary action and react with said reagent in said porous matrix if said analyte is present in said sample;
applying said sample to said second surface of said porous matrix;
taking an additional reflectance reading from said first surface after said sample is applied to said porous matrix;
comparing said additional reflectance reading to said first reflectance reading;

initiating said predetermined time period upon a predetermined drop in reflectance sufficient to indicate that said sample has reached said first surface;
and
taking a measurement reflectance reading at the end of
said predetermined time period without having determined the time at which said sample was initially applied to said porous matrix.
2. A method according to claim 1, wherein said reagent comprises [*69] a dye precursor bound to the matrix.